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# Ethical issues surrounding the implementation of long-acting injectable antiretroviral therapy in sub-Saharan Africa

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**Background:** This article discusses the ethical issues surrounding the integration of long-acting injectable antiretroviral therapy (LA-ART) in the programmatic management of human immunodeficiency virus (HIV). As the medical landscape evolves, implementing LA-ART introduces many ethical issues that should be considered for the success of scale-up in diverse settings.

**Methods:** This article examines key issues such as bioethical concerns around the rollout of LA-ART, including regulatory requirements, a person's autonomy, informed consent, privacy and confidentiality; the societal implications of providing LA-ART, including the impact on stigma and discrimination; ethics around who receives LA-ART, financial accessibility, equitable access, inclusive decision-making and cultural sensitivity; and the ethics of providing an expensive intervention, including cost-effectiveness, supply chain sustainability and resource allocation. By critically analysing the ethical issues, we aim to guide policymakers and identify areas for further research.

**Conclusion:** Our overarching aim is to ensure that the rights of people living with HIV are protected as implementors plan for the rollout of LA-ART with a focus on eastern and southern Africa. The utilization of LA-ART in resource-limited settings poses significant ethical challenges, necessitating careful consideration of autonomy, access and equity, stigma, discrimination, sustainability and treatment adherence.

**Keywords:** cabotegravir, ethics, HIV, injectable antiretroviral therapy, rilpivirine, sub-Saharan Africa.

## Background

Long-acting injectable antiretroviral (LA-ART) therapy offers an alternative to daily oral medication and potential improvements in adherence.[1] However, it introduces new challenges for people living with human immunodeficiency virus (HIV), including a strict injection schedule, increased clinic visits, potential complications such as injection site reactions and the risk of virological failure.[1]

Cabotegravir and rilpivirine (CAB/RPV) given in combination as a long-acting injectable formulation was approved by the US Food and Drug Administration (FDA) in 2021 for the management of adults (≥18 y of age) with HIV who are virally suppressed (HIV RNA level <50 copies/ml).[2] This novel treatment can be administered intramuscularly every 4 or 8 weeks, depending on patient/provider preference, and is now widely available in the USA and Europe.[3] Users must adhere to scheduled clinic appointments within 7 d, with delayed injections managed with oral

tablets. Fewer than 10% of participants in the three registrational trials (FLAIR [NCT02938520],[4] ATLAS [NCT02951052][5] and ATLAS 2M [NCT03299049][6]) were recruited from sub-Saharan Africa (SSA). Randomized controlled trials are currently being conducted in SSA with results likely to be available in late 2024 or 2025. The IMPALA trial (NCT05546242) aims to improve outcomes among people with a history of adherence challenges and is recruiting in Kenya, South Africa and Uganda. The LATA study (NCT05154747) in Kenya, South Africa, Uganda and Zimbabwe aims to evaluate the efficacy, safety and acceptability of LA-ART in adolescents. Findings from the CARES study conducted in Kenya, South Africa and Uganda were presented at the Conference on Retroviruses and Opportunistic Infections (Denver, CO, USA, 3–6 March 2024).

Simplified regimens are widely promoted to improve adherence, by reducing the frequency and complexity of medication regimens.[7] A study in Uganda among women who were lost to follow-up showed that despite poor knowledge of LA-ART, the participants reported high levels of perceived satisfaction and described injectables as more 'discreet' than pills, which may decrease the risk of stigma, discrimination or accidental disclosure of HIV status due to the discovery of pill bottles.[8] A qualitative study conducted among women demonstrated a willingness to use LA-ART because of the convenience, making it easier to integrate treatment into daily life.[9] Currently, social science substudies are integrated into ongoing trials in Africa, with a gap in the publication of qualitative studies within the region.

While injectables may be a game-changer for people dealing with pill fatigue, they raise some ethical concerns. We aim to provide an overview of key bioethical issues with the rollout of LA-ART and contribute to developing culturally appropriate strategies.

This article aims to provide a balanced evaluation of the ethical implications surrounding the rollout of LA-ART in SSA. Teleological ethics theory is relevant in understanding the goal and end purpose of LA-ART coupled with being in a position to weigh the benefits, such as the possibility of enhanced adherence, vs the potential drawbacks such as pain.[10] thus enabling policymakers, healthcare professionals and stakeholders to make informed decisions that prioritize the well-being of individuals and communities affected by HIV/acquired immunodeficiency syndrome.

## Ethical issues surrounding availability

### Regulatory requirements

Regulatory requirements remain critical for the LA-ART rollout. Although approved by the US FDA and European Medicines Agency, Botswana is the only African nation that has approved CAB/RPV, citing potential adherence benefits, however, delivery has not yet commenced.[11] Approval of LA-ART in Uganda is currently pending National Drug Authority approval. Most countries will await World Health Organization (WHO) recommendations before adapting their own HIV guidelines to accommodate LA-ART and LA-ART does not currently feature in any WHO guidelines.

### Financial accessibility

The individual costs associated with LA-ART could be a significant barrier for many people living with HIV. The demands of treatment, poverty, stigma and health system constraints pose monetary and psychosocial costs for many people living with HIV.[12] When determining the cost-effectiveness of rolling out LA-ART, it is important to consider transportation costs for care recipients due to increased clinic visits. Additionally, the loss of income resulting from taking time off work for these visits should also be taken into account. This consideration becomes even more relevant at a time when multimonth dispensing of oral ART is on the rise, allowing for up to a 6-months' supply of medication to be provided at once. Currently the cost of CAB/RPV in SSA is unknown. The list price in the USA is US$48 000/y and modelling has suggested that the treatment would need to cost <US$131/y to be considered cost-effective for individuals in Africa with high viral loads,[13] where oral ART currently costs US$43/y.[14]

In addition, the costs to the healthcare system should also be considered. Will CAB/RPV be obtained through usual mechanisms like the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria and will governments be able to sustain a supply of the treatment to the population? With many countries in SSA classified as low and middle income,[15] these questions need to be considered as LA-ART is integrated into clinical care. Ensuring accessibility and affordability is imperative to prevent further inequities in healthcare access.

### Equitable access

Equity requires that all individuals, regardless of socio-economic status or other characteristics, have equal access to LA-ART. Access to CAB/RPV remains a challenge because most of the stock produced is currently being used for research studies. CAB is being introduced for pre-exposure prophylaxis (PrEP), but because of cost, it is unlikely that there will be widespread access to CAB/RPV in Africa in the immediate future. Efficacy studies of CAB/RPV LA-ART are being conducted in SSA (IMPALA and LATA), but is it ethical to carry out a study on a population that may not easily access the intervention? In addition, the healthcare infrastructure in these African countries faces several challenges that could impede access to the intervention.[16]

A modelling study by Phillips et al.[13] indicated that the group that may benefit most from LA-ART are those with a viral load >1000 copies/ml (i.e. those with adherence challenges) and offering LA-ART to this group is likely to be the most cost-effective strategy. Will those who have been adherent to their treatment take this as a reward for those who were not adherent? Will people choose to be non-adherent to get relief from daily oral medication? This concern relates to the ethical principle of distributive justice, which observes fairness and equity in the allocation of resources, therefore inequalities in healthcare access due to affordability and availability must be addressed to uphold equity.

### Sustainability and resource allocation

The implementation of LA-ART raises concerns about the sustainability of resources. The long-term financial and infrastructural commitments required might strain healthcare systems. There are system-level challenges such as the requirement for clinic or hospital infrastructure (clean needles, trained staff, secure power and water supplies) for provider administration, the need for steady supply chains for the injectable ART (dependence

on a single manufacturer) and the requirement for a cold chain for transport of the ART and refrigeration at the site. There is also the requirement for HIV drug resistance testing potentially before and certainly during use, as well as laboratory monitoring during use, which would impose another burden on the limited resources.

Decentralization of care, including mobile health units with the capability to administer LA-ART should be considered to minimize prolonged travel to clinic sites.[17] However, concerns have been raised about sustainability regarding the cost of LA-ART, time and affordability after rollout for treatment and the increased staffing needs.[1,18] Ethically balancing resource allocation becomes a significant challenge in ensuring sustainability and fairness in healthcare distribution.

## Ethical issues surrounding patient selection and autonomy

### Patient autonomy

The principle of patient (or client) autonomy highlights each person's right to make knowledgeable, informed healthcare decisions for themselves. Respecting each person's autonomy can be difficult in practice, but is possible by involving people in their own healthcare planning, assessment and management.[19] However, with LA-ART, a person living with HIV may feel a loss of control over medical decisions because of the injectable treatment. In contrast to oral medication, injectable treatments require medical personnel to administer the medication. The need for regular clinic visits may present challenges for people who are mobile for work or have schedules that make adhering to clinic times a challenge.[20] This change from a more flexible schedule for accessing oral ART may affect a person's sense of responsibility and involvement in their care.

Conversely, disengaging from LA-ART also has implications. If one stops treatment, the extensive pharmacokinetic tail increases the risk of developing drug resistance.[21] This could lead to the transmission of drug-resistant viruses, including mutations that could evade CAB PrEP.[22] As noted above, LA-ART may therefore be less suited to people who travel frequently, making it challenging for them to attend clinic visits for injections. This creates a dilemma where the ethical principles of non-maleficence and autonomy clash and require careful balancing. Carillon et al.[23] note that maintaining the autonomy of a person living with HIV during the introduction of LA-ART requires consideration of communication and customizing treatment regimens to fit varied needs and wishes.

### Informed consent

The integration of LA-ART in the management of HIV raises crucial considerations related to informed consent, a fundamental bioethical principle. While LA-ART offers the advantage of alleviating the daily pill-related stress associated with oral ART, it introduces efficacy concerns compared with oral ART, potential side effects, apprehension about needles, injection frequency, injection site locations and clinic visits. Kanazawa et al.[1] advocates for addressing these concerns with potential recipients before initiation, emphasizing the importance of discussing alternatives and choices to facilitate an informed decision. Many low-income settings follow a public health approach to HIV whereby treatment is not individualized, but with the development of new treatments people living with HIV should be given a choice of either oral ART or LA-ART. Healthcare providers must engage in transparent dialogue with the persons receiving HIV care to uphold the ethical practice of informed and voluntary consent.[24]

### Stigma and discrimination

LA-ART could be a solution to the internalized stigma felt by people living with HIV and the discrimination they experience following inadvertent serostatus disclosure associated with oral treatments.[25] However, regular injections requiring more frequent visits to the HIV clinic may present privacy issues and the possibility of discrimination, especially in areas where there are high levels of stigma associated with HIV.[1] Although the injectable treatment aims to reduce stigma, the necessity of frequent clinic visits may have the opposite effect, potentially leaving individuals feeling exposed and vulnerable to judgment from coworkers and peers.[26] Those who have experienced such stigma and discrimination are less likely to have received appropriate clinical or medical care for their HIV.[27]

More frequent visits for LA-ART may have implications for client and healthcare worker time and providing injections may increase the workload of already stretched nurses. Promoting an inclusive healthcare environment that upholds the rights and dignity of people living with HIV is necessary to mitigate stigma and discrimination.

### Eligibility criteria

Currently LA-ART is the only combination approved as a complete regimen for the treatment of HIV in adults and adolescents ($\geq$35 kg and $\geq$12 y of age) who are virologically suppressed[18,28] with no known or suspected resistance to either drug.[29] This regimen is not suitable for individuals with chronic hepatitis B infection. Therefore, people living with HIV need to be informed that not all individuals will be eligible for treatment and further eligibility assessments may need to be performed.

### Cultural sensitivity

The selection of LA-ART should include input from diverse stakeholders, including representatives from the affected communities. Inclusivity entails consideration of the perspectives and needs of affected groups and prevention of the marginalization of certain populations. The ethical selection of LA-ART should account for cultural and social differences and preferences within diverse communities must be respected to avoid cultural bias.

## Ethical issues surrounding medication monitoring

### Risk of virological failure

The risk of virological failure in individuals who are eligible for LA-ART should be discussed at the onset of treatment. The injectable

**Table 1.** Summary of key ethical considerations and potential solutions

| Ethical considerations | Potential solutions |
|---|---|
| Diminished autonomy | Education and involvement, shared decision-making and regular follow-up and feedback with treatment recipients |
| Inequitable access to LA-ART | Implement mobile clinics that can reach underserved areas |
| Challenges to informed consent | Discussing alternatives and choices to facilitate an informed decision and continuous consenting processes |
| Stigma and discrimination | Education and awareness campaigns, peer-to-peer support services and community engagement |
| Risk of virological failure | Regular virological monitoring and personalized treatment plans |

regimen was found to be non-inferior to oral treatment in the registrational trials, but there is no evidence to suggest that the injectable form is more effective than oral pills when taken correctly, and the risk of failure may be even greater.[30]

While there are specific eligibility criteria established to reduce the risk of virological failure, the likelihood of such an outcome still stands at approximately 1.5%.[31] Consequently, there is a need to understand who is at risk of virological failure.[31,32] There is a need for the risk to be communicated to people offered LA-ART, as well as an understanding of how much risk the individuals would be exposed to and are willing to take, given that if they remain on effective oral therapy this risk is essentially averted.

The rollout of LA-ART across countries in SSA will be complex. It is uncertain whether in different countries it will be a phased approach where districts or provinces are considered at different points in time or if the rollout will be done simultaneously across an entire country. Can information from one health facility or district then be used to guide the rollout of others, and can the experience in one country inform practice in another? At present, there are no longitudinal real-world data from this setting.

Table 1 highlights the key ethical considerations in SSA along with the recommended potential solutions.

Below are some examples of where LA-ART has been implemented in SSA, to illustrate how some of the points raised above are being addressed. However, a number of these are exploratory implementation science projects with limited reach and sizeable budgets.

LA-ART is progressively being introduced in SSA to improve adherence to HIV treatment and reduce the burden of daily pills. In Kenya and South Africa, the CARES trial of CAB and RPV highlighted high levels of satisfaction of people receiving LA-ART and key-informant interviews identified the vital role of community health workers in the transition to injectable treatment.[33,34] In Uganda and South Africa, studies among adolescents and young adults showed improved adherence and reduced stigma and could guide implementation of similar studies.[35–37] In Tanzania, a mixed-methods study was undertaken involving female sex workers. The results indicated a significant preference for LA-ART over daily oral medication should the option be available.[26,38] In coastal Kenya, focus groups were conducted with people living with HIV, including both male and female youth and adults, men who have sex with men and female sex workers. These groups also held positive attitudes toward LA-ART, anticipating it would reduce pill burden and stigma and improve adherence.[38–40] These examples highlight the need for effective community engagement, education and tailored strategies in addressing challenges in HIV care.

## Discussion

The utilization of LA-ART in resource-limited settings poses significant ethical challenges, necessitating careful consideration of patient/client autonomy, access, equity, stigma, discrimination, sustainability and treatment adherence. Financial accessibility is a primary concern, given the strain on limited healthcare budgets due to the high cost of procurement, distribution and administration. Logistical challenges arise from inadequate healthcare infrastructure, encompassing cold chain maintenance, healthcare provider training and necessary infrastructure upgrades.[41] Economic inequality can worsen access issues, as individuals in lower socio-economic strata may be unable to afford transportation to healthcare facilities or the costs associated with accessing LA-ART and may prioritize basic needs over health services. Resource prioritization can lead to an inequitable distribution of healthcare resources by directing funds and services primarily to areas or populations deemed more valuable. This often results in urban centres receiving a disproportionate share of healthcare resources, while rural and underserved communities are left with inadequate support.

Capacity building for the workforce is crucial to proficiently administer and monitor LA-ART. Monitoring user adherence, supply chain management, community engagement and education are all essential to ensure successful program integration. Evidence-based decision-making relies on regulatory approval, policy frameworks, research and sound data collection, including observational data from routine care settings. Long-term sustainability mandates sustained financial and political commitments. Achieving global health equity necessitates collaboration among governments, international organizations and pharmaceutical companies to provide equitable access to advanced treatments.

International organizations such as WHO and PEPFAR play a crucial role in ensuring equitable access to LA-ART in SSA by providing funding, technical support and policy guidance. Additionally, these organizations can facilitate partnerships between governments and local communities to enhance education and awareness about LA-ART, addressing stigma and discrimination. By promoting evidence-based practices and supporting

regulatory frameworks, organizations like WHO and PEPFAR can help streamline the integration of LA-ART into existing healthcare systems, ensuring that all populations, particularly marginalized groups of people living with HIV, have access to these advanced treatments.

## Conclusions

The integration of LA-ART into healthcare systems in resource-limited settings presents both ethical challenges and opportunities for advancing health equity. It is critical to ensure the rights of clients are protected. While financial accessibility, healthcare infrastructure and capacity building are critical factors that must be addressed, the role of international organizations like WHO and PEPFAR is vital in facilitating this integration. To address these concerns effectively, a holistic approach prioritizing user education, equal access, client rights and sustainable healthcare practices is essential. Navigating these ethical challenges carefully is crucial for ensuring both the success and moral soundness of integrating LA-ART into healthcare systems.

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